



United Phosphorus, Inc.

630 Freedom Business Center
Suite 402
King of Prussia, PA 19406
(610) 491-2828 (phone)
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Rebecca A. Clemmer
Regulatory Manager

July 7, 2017

Jordan Page, Chemical Review Manager
Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: 90-Day Response to GDCI-110601-1697 for Ethofumesate

Dear Ms. Page:

Attached please find the United Phosphorus, Inc. response and all forms as required. United Phosphorus, Inc. has offered to share the costs of data development for most studies, but will be submitting two existing studies.

Please contact me if you have any questions.

Very truly yours,

Rebecca A. Clemmer
rebecca.clemmer@uniphos.com



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Rebecca A. Clemmer
Regulatory Manager

This information is submitted in support of the Ethofumesate GDCI 110601-1697.

ACKNOWLEDGEMENT OF RECEIPT**DCI Number: GDCI-110601-1697****Data Call-In Information**

Company Name	UNITED PHOSPHORUS, INC
Company Address	630 FREEDOM BUSINESS CENTER, SUITE 402 KING OF PRUSSIA, PA 19406
DCI Type	Generic
Issued Date	03/09/2017
90-Day Response Deadline	06/17/2017
CRM Information	Jordan Page
Chemical Name	Ethofumesate
Chemical Number	110601
EPA Registration Number(s)	70506-105
Guideline Number(s)	835.4100; 835.4200; 835.4300; 835.4400; 850.1010; 850.1350; 850.2100; 850.2200; 850.3040; 850.4500; 850.4550; 860.1340; 875.2100; SS-1254; SS-1317; SS-1318; SS-1319; SS-1353
Submitted Date	03/13/2017

Acknowledgement of Receipt:

I, Mrs. Rebecca Clemmer, have received from U.S. EPA's Office of Pesticide Programs the pesticide DCI (GDCI-110601-1697) for Ethofumesate on 03/09/2017 for UNITED PHOSPHORUS, INC. Additionally, I have reviewed the Data Call-In information.

90-DAY RESPONSE**DCI Number: GDCI-110601-1697****Data Call-In Information**

Company Name	UNITED PHOSPHORUS, INC
Company Address	630 FREEDOM BUSINESS CENTER, SUITE 402 KING OF PRUSSIA, PA 19406
DCI Type	Generic
Issued Date	03/09/2017
90-Day Response Deadline	06/17/2017
CRM Information	Jordan Page
Chemical Name	Ethofumesate
Chemical Number	110601

90-Day Response Information

Tracking Number	CDX_DCI_2017_000585
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DCI Level Documents

File Name	File Type	MRID	CBI	Submitted Date
Cover letter-signed.pdf	Submission Cover Letter	N.A.	N	07/07/2017

EPA Product Registration Number(s)

70506-105	I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."
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Guideline Requirement Number(s)**Guideline Requirement Number - 835.4100**

Study Title	Aerobic soil metabolism
Protocol	N
Target Submission Date	03/09/2019
Use Pattern	A; C
Test Substance	TGAI or PAIRA
Time Frame	24 month(s)
Footnote(s)	2. Two additional soils.

Registrant Response		Offer to Cost Share		
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
General Correspondence.pdf	General Correspondences	N.A.	N	07/07/2017
Form 8570-32 Attempt to Enter.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	N	07/07/2017
Guideline Requirement Number - 835.4200				
Study Title	Anaerobic soil metabolism			
Protocol	N			
Target Submission Date	03/09/2019			
Use Pattern	A; C			
Test Substance	TGAI or PAIRA			
Time Frame	24 month(s)			
Footnote(s)	9. Three soils.			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
General Correspondence.pdf	General Correspondences	N.A.	N	07/07/2017
Form 8570-32 Attempt to Enter.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	N	07/07/2017
Guideline Requirement Number - 835.4300				
Study Title	Aerobic aquatic metabolism			
Protocol	N			
Target Submission Date	03/09/2019			
Use Pattern	A; C			
Test Substance	TGAI or PAIRA			
Time Frame	24 month(s)			

Footnote(s)				
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
General Correspondence.pdf	General Correspondences	N.A.	N	07/07/2017
Form 8570-32 Attempt to Enter.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	N	07/07/2017
Guideline Requirement Number - 835.4400				
Study Title	Anaerobic aquatic metabolism			
Protocol	N			
Target Submission Date	03/09/2019			
Use Pattern	A; C			
Test Substance	TGAI or PAIRA			
Time Frame	24 month(s)			
Footnote(s)				
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
General Correspondence.pdf	General Correspondences	N.A.	N	07/07/2017
Form 8570-32 Attempt to Enter.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	N	07/07/2017
Guideline Requirement Number - 850.1010				
Study Title	Aquatic invertebrate acute toxicity, test, freshwater daphnids			
Protocol	N			
Target Submission Date	03/09/2018			
Use Pattern	A; C			
Test Substance	TGAI			

Time Frame	12 month(s)			
Footnote(s)				
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
General Correspondence.pdf	General Correspondences	N.A.	N	07/07/2017
Form 8570-32 Attempt to Enter.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	N	07/07/2017
Guideline Requirement Number - 850.1350				
Study Title	Mysid chronic toxicity test			
Protocol	N			
Target Submission Date	03/09/2018			
Use Pattern	A; C			
Test Substance	TGAI			
Time Frame	12 month(s)			
Footnote(s)	15. Preferred test species is mysid shrimp (Mysidopsis bahia)			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
General Correspondence.pdf	General Correspondences	N.A.	N	07/07/2017
Form 8570-32 Attempt to Enter.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	N	07/07/2017
Guideline Requirement Number - 850.2100				
Study Title	Avian acute oral toxicity test			
Protocol	N			
Target Submission Date	03/09/2018			
Use Pattern	A; C			

Test Substance	TGAI
Time Frame	12 month(s)
Footnote(s)	11. Test species is passerine species.
Registrant Response	Offer to Cost Share

Uploaded Documents

File Name	File Type	MRID	CBI	Submitted Date
General Correspondence.pdf	General Correspondences	N.A.	N	07/07/2017
Form 8570-32 Attempt to Enter.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	N	07/07/2017

Guideline Requirement Number - 850.2200

Study Title	Avian dietary toxicity test
Protocol	N
Target Submission Date	03/09/2018
Use Pattern	A; C
Test Substance	DEGR
Time Frame	12 month(s)
Footnote(s)	13. Test material is NC 8493. 18. Data are preferred on mallard or bobwhite quail.
Registrant Response	Offer to Cost Share

Uploaded Documents

File Name	File Type	MRID	CBI	Submitted Date
General Correspondence.pdf	General Correspondences	N.A.	N	07/07/2017
Form 8570-32 Attempt to Enter.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	N	07/07/2017

Guideline Requirement Number - 850.3040

Study Title	Field testing for pollinators
Protocol	Y

Target Submission Date	03/09/2019			
Use Pattern	A; C			
Test Substance	TEP			
Time Frame	24 month(s)			
Footnote(s)	<p>1. USEPA. 2012c. "Field Testing for Pollinators." Ecological Effects Test Guidelines OCSPP 850.3040. EPA 712-C-017</p> <p>3. Tier III study. The need for a field test for pollinators will be determined based on the results of lower-tiered tests and/or other lines of evidence and the need for a refined pollinator risk assessment.</p> <p>14. See information and guidance identified in the EPA documents, (i) USEPA. 2012. White Paper in Support of the Proposed Risk Assessment Process for Bees. Submitted to the FIFRA Scientific Advisory Panel for Review and Comment September 11-14, 2012. Office of Chemical Safety and Pollution Prevention Office of Pesticide Programs Environmental Fate and Effects Division, Environmental Protection Agency, Washington DC; Environmental Assessment Directorate, Pest Management Regulatory Agency, Health Canada, Ottawa, CN; California Department of Pesticide Regulation; (ii) 2014 Guidance for Assessing Pesticide Risks to Bees. Office of Pesticide Programs United States Environmental Protection Agency, Health Canada Pest Management Regulatory Agency, California Department of Pesticide Regulation. June 19, 2014. https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf</p> <p>22. A study protocol must be submitted to, and reviewed by EPA, prior to study initiation.</p>			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
General Correspondence.pdf	General Correspondences	N.A.	N	07/07/2017
Form 8570-32 Attempt to Enter.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	N	07/07/2017
Guideline Requirement Number - 850.4500				
Study Title	Algal Toxicity			
Protocol	N			
Target Submission Date	03/09/2018			
Use Pattern	A; C			
Test Substance	TGAI			
Time Frame	12 month(s)			
Footnote(s)	12. Test species are freshwater and marine diatom.			

Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
General Correspondence.pdf	General Correspondences	N.A.	N	07/07/2017
Form 8570-32 Attempt to Enter.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	N	07/07/2017
Guideline Requirement Number - 850.4550				
Study Title	Cyanobacteria (Anabaena flos-aquae) Toxicity			
Protocol	N			
Target Submission Date	03/09/2018			
Use Pattern	A; C			
Test Substance	TGAI			
Time Frame	12 month(s)			
Footnote(s)				
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
General Correspondence.pdf	General Correspondences	N.A.	N	07/07/2017
Form 8570-32 Attempt to Enter.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	N	07/07/2017
Guideline Requirement Number - 860.1340				
Study Title	Residue analytical method			
Protocol	N			
Target Submission Date	03/09/2019			
Use Pattern	A; C			
Test Substance	TGAI, Degr			
Time Frame	24 month(s)			

Footnote(s)	10. Test substance is TGAI and degradates of concern NC 8493, NC 9607, and NC 20645			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
General Correspondence.pdf	General Correspondences	N.A.	N	07/07/2017
Form 8570-32 Attempt to Enter.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	N	07/07/2017
Guideline Requirement Number - 875.2100				
Study Title	Foliar dislodgeable residue dissipation			
Protocol	N			
Target Submission Date	03/09/2018			
Use Pattern	A; C			
Test Substance	TEP			
Time Frame	12 month(s)			
Footnote(s)	19. And turf transferable residues			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
General Correspondence.pdf	General Correspondences	N.A.	N	07/07/2017
Form 8570-32 Attempt to Enter.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	N	07/07/2017
Guideline Requirement Number - SS-1254				
Study Title	Adult honeybee chronic oral toxicity			
Protocol	Y			
Target Submission Date	03/09/2018			
Use Pattern	A; C			

Test Substance	TGAI
Time Frame	12 month(s)
Footnote(s)	6. Tier I study. OECD has not yet finalized test guidelines for chronic studies, and efforts are underway to develop standardized guidelines for assessing the effects from chronic exposure to adult and larvae in the laboratory. Discussion of the study design elements for the 10-day adult toxicity test can be found in Appendix O of the European Food Safety Authority (EFSA) guidance document: EFSA. Guidance on the risk assessment of plant protection products on bees (<i>Apis mellifera</i> , <i>Bombus</i> spp. and solitary bees. EFSA Journal 2013;11(7):3295, 266 pp. doi:10.2903/j.efsa.2013.3295. Available online at: http://www.efsa.europa.eu/en/efsajournal/doc/3295.pdf 22. A study protocol must be submitted to, and reviewed by EPA, prior to study initiation.
Registrant Response	Developing Data
Guideline Requirement Number - SS-1317	
Study Title	Honey bee larval acute oral toxicity
Protocol	Y
Target Submission Date	03/09/2018
Use Pattern	A; C
Test Substance	TGAI
Time Frame	12 month(s)
Footnote(s)	8. Tier I study. OECD Test Guideline 237 may be used to develop a protocol for this study (OECD. 2013 Guidelines for Testing Chemicals. Honey bee (<i>Apis mellifera</i>) larval toxicity test, single exposure.) See: http://www.oecd-ilibrary.org/environment/test-no-237-honey-bee-apis-mellifera-larval-toxicity-test-single-exposure_9789264203723-en
Registrant Response	Developing Data
Guideline Requirement Number - SS-1318	
Study Title	Honey bee larval chronic oral toxicity
Protocol	Y
Target Submission Date	03/09/2018
Use Pattern	A; C
Test Substance	TGAI
Time Frame	12 month(s)

Footnote(s)	<p>7. Tier I study. OECD has not yet finalized test guidelines for chronic studies with honey bee larvae. OECD Draft Guidance Document Honey Bee (<i>Apis mellifera</i>) Larval Toxicity Test, Repeated Exposure. https://www.oecd.org/env/ehs/testing/Honeybee%20larval%20rep%20expo_REV%20following%20April%202015%20expert%20meeting_Draft%2020%20July%202015.pdf 22. A study protocol must be submitted to, and reviewed by EPA, prior to study initiation.</p>			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
General Correspondence.pdf	General Correspondences	N.A.	N	07/07/2017
Form 8570-32 Attempt to Enter.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	N	07/07/2017
Guideline Requirement Number - SS-1319				
Study Title	Semi-field testing for pollinators (tunnel or colony feeding studies)			
Protocol	Y			
Target Submission Date	03/09/2019			
Use Pattern	A; C			
Test Substance	TEP			
Time Frame	24 month(s)			
Footnote(s)	<p>5. Tier II study. The need for a semi-field test for pollinators (i.e., either a field-feeding test or a tunnel test) will be determined based on the results of lower-tiered tests and/or other lines of evidence, and the need for a refined pollinator risk assessment. 16. Formal guidelines for semi-field tests do not yet exist; however, information that can help guide the development of either a semi-field tunnel test protocol can be found at OECD 75, see: OECD. 2007. Series on Testing and Assessment Number 75. Guidance document on the honey bee (<i>Apis mellifera</i> L.) brood test under semi-field conditions. Environmental Directorate Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. ENV/JM/MONO(2007)22. 31-Aug-2007. http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)22&doclanguage=en. 17. For field-feeding studies see: Oomen et al. 1992: Oomen, P. A. A. DeRuijter and J. Van der Steen. 1992. Method for honey bee brood feeding tests with insect growth-regulating insecticides. Bul OEPP/EPPO Bulletin 22: 613 - 616. 21. A study protocol must be submitted to, and reviewed by EPA, prior to study initiation.</p>			
Registrant Response	Offer to Cost Share			
Uploaded Documents				

File Name	File Type	MRID	CBI	Submitted Date
General Correspondence.pdf	General Correspondences	N.A.	N	07/07/2017
Form 8570-32 Attempt to Enter.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	N	07/07/2017
Guideline Requirement Number - SS-1353				
Study Title	Residues in pollen and nectar			
Protocol	Y			
Target Submission Date	03/09/2019			
Use Pattern	A; C			
Test Substance	TEP			
Time Frame	24 month(s)			
Footnote(s)	<p>4. Tier II study. The need for this study will be determined based on the results of lower-tiered studies and/or other lines of data and the need for a refined pollinator risk assessment.</p> <p>20. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation. The following elements could be considered when developing study protocol(s) for the monitoring of residues in pollen/nectar.</p> <ul style="list-style-type: none"> o Consideration of the range of application methods and environmental conditions (e.g., soil and hydric regimes) that the target crop(s) may be under. o Consideration of the attractiveness of the selected crop to pollinators. o Consideration of a collection schedule sufficient to allow for an understanding of the character of residues, in the pollen/nectar and/or plant tissues, over time. o Consideration of data sufficient to determine whether residues of the active ingredient and/or degradation product(s) accumulates in soil and is/are bioavailable for plant to uptake in a following planting, and therefore result in potential exposure to pollinators. o Consideration of the market proportion of the selected target crop(s). 			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
General Correspondence.pdf	General Correspondences	N.A.	N	07/07/2017
Form 8570-32 Attempt to Enter.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	N	07/07/2017
Submitter Information				
Submitter	Rebecca Clemmer			

Submitted Date	07/07/2017
Additional Contact(s)	rebecca.clemmer@uniphos.com



United States Environmental Protection Agency
Washington, D.C. 20460

CERTIFICATION OF ATTEMPT TO ENTER INTO AN
AGREEMENT WITH REGISTRANTS FOR
DEVELOPMENT OF DATA

Form Approved.

OMB Nos. 2070-0057;
2070-0107; 2070-0122;
2070-0164

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 15 minutes per response including time for reading the instructions, searching existing data sources, gathering and maintaining the data needed and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

Please fill in blanks below

Company Name

United Phosphorus, Inc.

Company Number

70506

Chemical Name

Ethofumesate

EPA Chemical Number

110601

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Rodenticide and Fungicide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)

Bayer Cropscience LP
Willowood Ethofumesate LLC

Date of Offer

July 7, 2017

Certification:

I certify that I am duly authorized to represent the company name above, and that the statements that I have made on this form and all attachments therein are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative

Date

July 7, 2017

Name and Title (Please Print or Type)

Rebecca A. Clemmer, Regulatory Manager